



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Telephone (973) 526-6002

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

February 1, 2007

File # 07-NWJ-07

John Warehime, President/CEO  
Hanover Foods Corporation  
1550 York Street  
Hanover, PA 17331

Dear Mr. Warehime:

The Food and Drug Administration (FDA) conducted an inspection of your subsidiary company, Aunt Kitty's Foods, Inc., located at 270 North Mill Road, Vineland, New Jersey on August 16, 17 and 21, 2006. At the close of the inspection, we collected a sample of the [REDACTED] brand White Clam Italian Style Pasta Sauce (15 oz), lot number VM 6111 126622 MAY 2009, manufactured by Aunt Kitty's Foods, Inc, to determine compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and FDA's food labeling requirements (21 CFR Part 101 – Food Labeling). You can find the Act and FDA's regulations through links on FDA's Internet web site at <http://www.fda.gov>

FDA analyzed the sample of your [REDACTED] brand White Clam Italian Style Pasta Sauce distributed by [REDACTED] to determine whether the nutrition information on your Nutrition Facts panel accurately reflects the nutrient content of the product. During the inspection, we further determined that Aunt Kitty's was responsible for verifying the nutrition information listed on the product label. The product label states that one serving (111 g) contains 25% of the percent daily value (DV) of iron. The analyzed content of your white clam sauce was found to contain 8.8% (original analysis) and 13.3% (check analysis) of the amount of iron declared on the label. Therefore, your product is misbranded under section 403(a)(1) of the Act [21 U.S.C. 343(a)(1)] in that the labeling

is false and misleading because the amount of iron present is less than 80 percent of the amount declared [see 21 CFR 101.9(g)(4)(ii)].

You should take prompt action to correct the deviation. Failure to promptly correct this deviation may result in regulatory action without further notice, such as seizure of your product.

You should notify this office in writing within 15 working days of receipt of this letter, of any corrective actions, including an explanation of each step being taken to prevent the recurrence of similar conditions. If corrective action cannot be completed within 15 working days, state the reason for the delay.

As some general information, section 201(qq) of the Act [21 U.S.C. 321(qq)] defines as major food allergens milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

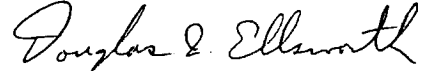
- (1) The word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients (section 403(w)(1)(A) of the Act [21 U.S.C. 343(w)(1)(A)]); or
- (2) The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen) (section 403(w)(1)(B) of the Act [21 U.S.C. 343(w)(1)(B)]).

In order to ensure uniformity in the presentation of the major food allergens under FALCPA, a "Contains" statement that immediately follows the ingredient list should only include a listing of the major food allergens specified in FALCPA that are in the food. We point out that clams are not a major food allergen under FALCPA. Additional information about FALCPA is available on the FDA website at <http://www.cfsan.fda.gov/~dms/wh-alrgy.html>.

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Hanover, PA  
February 1, 2007  
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Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Boulevard, 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054, Attention Douglas C. Kovacs, Acting Compliance Officer. If you have any questions, please contact Mr. Kovacs at 973 526-6070 ext. 3006.

Sincerely,



Douglas I. Ellsworth  
District Director  
New Jersey District

Cc: Edward Boeckel, General Manager  
Aunt Kitty's Foods, Inc.  
270 North Mill Road  
Vineland, NJ 08360

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[REDACTED]  
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